

### **REMARKS/ARGUMENTS**

Claims 1, and 4-25 are presented for Examiner Erez's consideration. Applicants' attorney thanks the Examiner for his comments. Applicants' attorney notes the Examiner's statement that Claim 18 continues to be allowed over the prior art of record.

Pursuant to 37 C.F.R. § 1.111, reconsideration of the present application in view of the foregoing amendments and the following remarks is respectfully requested.

By way of the Office Action mailed September 16, 2005, Examiner Erez rejected claims 1-17, and 19-21 under 35 U.S.C. §102 as allegedly being anticipated by U.S. Patent Number 5,343,857 to Schneider et al.

By way of the Office Action mailed October 4, 2004, Examiner Erez rejected claims 22-25 under 35 U.S.C. §103 as allegedly being obvious to one of ordinary skill in the art at the time the invention was made and thus unpatentable over U.S. Patent Number 5,343,857 to Schneider et al in view of U.S. Patent Number 6,168,758 to Forsberg et al.

Applicants traverse both rejections in their entirety.

#### **35 USC §102 Rejections:**

As is understood from MPEP §2131, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

The Examiners argument seems to focus on the position that "Schneider teaches an apparatus...wherein the valve is still fully capable of being opened by the catheter...". To support such an argument, the Examiner formulates a scenario in which the catheter is made to "be the first structure to engage valve 20,19 **when the adapter and manifold are connected as per the modification...**" This line of argumentation fails for multiple reasons.

It appears that the Examiner is making an inherency argument, i.e., that the "claimed and prior art products are identically or substantially identical." The

Examiner is comparing the functionality of the prior art with the present invention when he states that the prior art "is still fully capable of being opened". In making this comparison, the Examiner is attempting to cite structure in the prior art and equate its functionality to structures claimed in the present invention. However, as stated in MPEP §2114, "Apparatus claims cover what a device is, not what a device does." Moreover, "an apparatus must be distinguished from the prior art in terms of structure rather than function". "Even if the prior art device performs all the functions recited in the claim, the prior art cannot anticipate the claim if there is any structural difference". As such, in the present case, any anticipation based on inherency must necessarily fail.

Furthermore, in making the Examiner's proposed modification, the Examiner is wholly changing the intent of the Schneider patent. Throughout the entire Schneider reference, it is specified that the adapter is designed to be capable of sealing the port and opening while maintaining manifold pressure integrity. See for example, column 2, lines 56-61. At column 4, lines 5-8 it states that a male adapter is provided for air-tight attachment to the manifold. Perhaps even more critically, at column 2, lines 50-68, it is described that "***prevailing respiratory support techniques have made it disadvantageous to interrupt respiratory support by opening the manifold to the atmosphere.***" (emphasis added). Reading the entire disclosure of column 5 one skilled in the art would understand that "valve 16 (as shown in FIG. 2) maintains the interior of the manifold **isolated from the atmosphere at all times**" as stated at lines 9-12 (emphasis added). Lines 25-30 describe how the valve structure "**prevents passage of gases through the valve 16 under all normally occurring pressure differentials**" (emphasis added). At lines 50-53 it is stated that the adapter 11 working in conjunction with the sheath 22 is also "**designed to isolate the suction catheter 23 from the atmosphere**" (emphasis added). At column 5, line 61 through column 6, line 5, a description of how the adapter is engaged with the manifold is set forth in detail. At column 6, lines 6-18 it is again emphasized that

As is readily evident, during insertion of the adaptor 11 into the access port 15, **the sealing relationship formed between the valve 16 and the adaptor 11 during the initial phase of insertion, prior to opening of the top portion 20 of the valve 16, is intended to completely isolate the interior of the manifold 10 from the atmosphere during attachment of the accessory device.** (emphasis added)

In fact, one of the main intents of the Schneider reference is to fulfill a need "for a respiration system which includes a respiratory manifold which allows simple attachment and detachment of accessory devices during continuous patient respiratory support ***without substantial pressure loss from the system...***". (emphasis added) Column 2, lines 32-37. This is confirmed in the spirit and scope of the invention paragraph found at column 6, lines 40-50 that attempts to describe various unspecified modifications by the statement that modifications can be made so long as they maintain isolation of the respiratory system from the atmosphere. Moreover, this is reiterated once again at column 6, lines 60-63 where it is discussed on how to disengage the device.

Nevertheless for the sake of argument, were the catheter to be advanced "past adapter 11 so that the catheter would be located outside the adapter (i.e., as shown in Fig. 3, moving the catheter to the left prior to connecting the catheter to the manifold)" as suggested by the Examiner, the apparatus would not conform to the purpose and intent of the Schneider disclosure. It is arguably conceivable that in the Examiner's modification, the catheter 23 would be the first structure to engage the valve and thus the catheter would be the structure which opened the valve. However, advancing the catheter past the adapter would result in air infiltration and affect manifold pressure integrity, clearly a result wholly against the intent of the Schneider reference.

The Examiner also maintains that Schneider teaches a valve comprising at least one protrusion, i.e., the tip of valve 20,19, on at least one surface of the valve. Moreover, the Examiner states that the valve is a flap which is both pivotably connected to the manifold and disk-shaped. These statements appear to be mischaracterizations of the structure of the Schneider reference. The Schneider valve has no protrusions, the Examiner refers to the top portion 20 which is merely

a structure that is normally constricted in a closed configuration to prevent the passage of gases therethrough as stated at column 5, lines 25-30 and when stretched by the adapter forms the circumference of an opening through which the catheter passes as described at column 6, lines 3-4. The Schneider reference also fails to disclose or suggest any valve configured as a flap. In contrast, the Schneider valve 16 has a base portion 17 which "is fixed to the distal end 18 of the port 15 in a permanent, air-tight manner, such as by an adhesive or the like" as stated at column 5, lines 21-23. ***This structure is more reminiscent of a stretched membrane*** in that it is secured to the manifold about its entire periphery and not pivotably connected as stated by the Examiner. Furthermore, the Schneider valve 16 is not disk shaped either as indicated by the Examiner. As stated at column 5, lines 23-24, "the central portion 19 of the valve 16 is generally conical in shape". As such, it should be clear that the present invention is structurally dissimilar to the Schneider apparatus.

Moreover, by making the proposed modifications to the operation of the Schneider reference, the Schneider reference would not function in accordance with its intent. Additionally, as stated, the structure of the present invention is considerably different from Schneider. As such, the claims of the present invention cannot be anticipated by Schneider since Schneider fails to teach each and every element as set forth in the present claims, either expressly or inherently.

In addition, the claims in the present invention have been further amended to even more clearly define them over the prior art. For example, claim 1 as amended recites in pertinent part:

...wherein the valve is a flap movable between a first, distal position and a second, proximal position, and the flap is configured such that the ***at least one protrusion engages the distal end of the catheter as the catheter is advanced through the valve so as to maintain a space between the flap valve and the distal end of the catheter*** (emphasis added).

The structure claimed in this amendment may be found throughout the specification, and particularly at page 2, line 30 through page 3, line 3. The reason for this is structure is to "minimize the amount of mucus and similar secretions that collect or

coat the distal surface of the flap valve during retraction or withdrawal of the catheter" as recited on page 3, lines 4-6. The remaining rejected independent claims now contain a similar amendment, and as such the same argument would apply.

In contrast, by sliding the Schneider catheter 23 through the valve opening at the top portion 20 of valve 16 as proposed by the Examiner, subsequent withdrawal of the catheter would strip the mucus off on the distal side of the valve at the elements referred to as "protrusions" by the Examiner. This would be in direct opposition of the intended purpose of the present invention. As such, it should be apparent that not only structurally but functionally, the present invention differs from Schneider.

Since the Applicant contends that the independent claims are not anticipated by Schneider, and all dependent claims carry the same limitations as their respective independent claim, accordingly, it is respectfully submitted that the Examiner's rejection of Claims 1, 4-17 and 19-21 should be withdrawn.

### **35 USC §103 Rejections:**

With respect to the rejection of claims 22-25 over Schneider in view of Forsberg, it is submitted that as discussed above the Schneider patent fails to teach or suggest each and every element which is present in the claims of the present invention, and Forsberg fails to provide a teaching or suggestion of the elements which Schneider fails to teach or suggest. Where the cited references fail to teach or suggest each of the claimed elements to one skilled in the art, the rejection must fail. Accordingly, it is respectfully submitted that the Examiner's rejection of Claims 22-25 should be withdrawn.

Applicants respectfully request the rejections of the claims under 35 U.S.C. §§ 102 and 103 be withdrawn in light of the preceding amendments and remarks.

For the foregoing reasons, the application and claims are believed to be in condition for allowance and such action is respectfully requested. However, should any questions arise with regard to this matter the Examiner is encouraged to contact

the undersigned at (770)-587-8621 or fax number (770) 587-7324. Please charge any other prosecutorial fees including one month's late fee which are due to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875.

Respectfully submitted,

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I, Laura L. Rubino, hereby certify that on Friday, January 13, 2006 this document is being transmitted via facsimile to the Commissioner for Patents, United States Patent and Trademark Office, Central Fax No. 571-273-8300.

By:



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